

# EXHIBIT 10

Appln. No.: 14/713,643  
Amendment Dated September 28, 2016  
Reply to Office Action of July 12, 2016

TEVE-139US12

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

Appln. No: 14/713,643  
Applicant: Declan Walsh et al.  
Filed: May 15, 2015  
Title: DOSE COUNTERS FOR INHALERS, INHALERS AND METHODS OF ASSEMBLY  
THEREOF  
T.C./A.U.: 2876  
Examiner: Daniel A. Hess  
Confirmation No.: 4229  
Docket No.: TEVE-139US12

**AMENDMENT**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Commissioner:

Responsive to the Office Action dated July 12, 2016, please amend the above-identified application as follows:

- ☐ **Amendments to the Specification** begin on page of this paper.
- ☒ **Amendments to the Claims** are reflected in the listing of claims which begins on page 2 of this paper.
- ☐ **Amendments to the Drawings** begin on page of this paper and include an attached replacement sheet(s).
- ☐ **Amendments to the Abstract** are on page of this paper. A clean version of the Abstract is on page of this paper.
- ☒ **Remarks/Arguments** begin on page 3 of this paper.

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**Amendments to the Claims:** This listing of claims will replace all prior versions and listings of claims in the application.

Listing of Claims:

1. (Currently Amended) A method of assembling an inhaler for inhaling medicament, the inhaler having a body for retaining a medicament store and a dose counter having a moveable actuator and a chassis mounted on the body, said method comprising:

inserting a plurality of pins on one of the body and the chassis into a plurality of mating apertures on the other of the body and the chassis before heat staking the chassis in place, wherein either the plurality of pins or the plurality of mating apertures are positioned on three different sides of the chassis; and

heat staking the chassis of the dose counter onto the body by heat staking the plurality of pins in their respective mating apertures.

2. (Original) The method as claimed in claim 1 further comprising the step of mounting a spring-retained ratchet actuator in the body before heat staking the chassis in place.

3. (Cancelled)

4. (Cancelled)

5. (Original) The method as claimed in claim 1, wherein the dose counter is positioned in a dose counter chamber of the body, and the method further comprises the step of mounting a cover on the body to conceal the dose counter chamber of the body.

6. (Original) The method as claimed in claim 5, wherein the mounting step includes mounting the cover such that it does not conceal a perforation that is defined at the open end of the dose counter chamber, wherein the perforation permits the evaporation of water or aqueous matter in the dose counter chamber into the atmosphere.

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**Remarks/Arguments:**

***Claim Status***

Claims 1, 2, 5 and 6 are pending and stand rejected. Claims 3 and 4 have been incorporated into claim 1, and those claims have been cancelled without prejudice or disclaimer of the subject matter thereof. Claim 1 has been additionally amended to recite that "either the plurality of pins or the plurality of mating apertures are positioned on three different sides of the chassis." This feature can be found, for example, in FIG. 6B (see apertures 188, 190 and 192), FIG. 8B (see pins at 182, 184 and 186) and the description accompanying those figures. No new matter has been added.

***Claim Rejections***

Claims 1-6 stand rejected as being obvious over the combination of U.S. Patent App. Pub. No. 2012/0006322 to Anderson and U.S. Patent No. 6,446,627 to Bowman. The Applicant respectfully requests reconsideration of this rejection for the reasons set forth hereinafter.

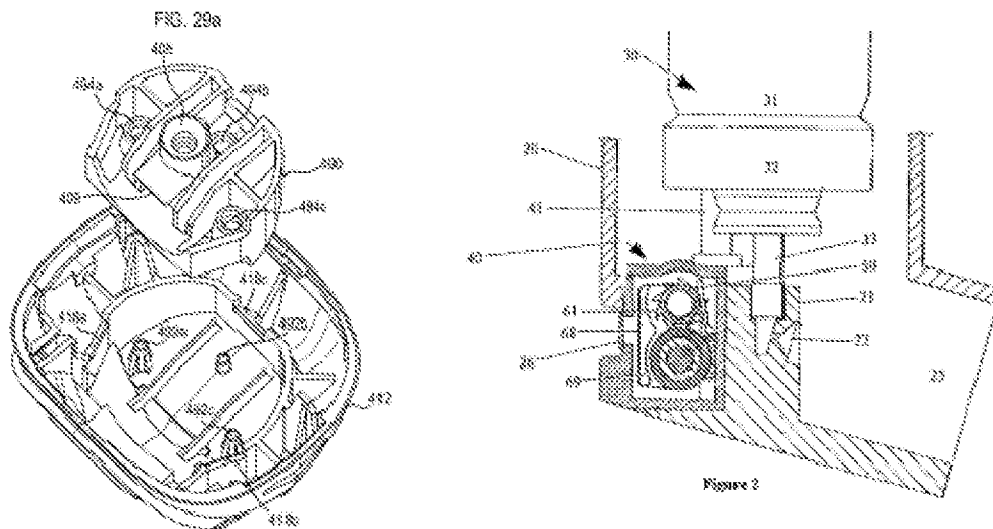
In establishing a prima facie case of obviousness, "all of the claim limitations must be considered." M.P.E.P. §2143. Sole independent claim 1 has been amended and recites features that are neither disclosed nor suggested by the cited references, namely,

A method of assembling an inhaler for inhaling medicament, the inhaler having a body for retaining a medicament store and a dose counter having a moveable actuator and a chassis mounted on the body, said method comprising inserting a plurality of pins on one of the body and the chassis into a plurality of mating apertures on the other of the body and the chassis before heat staking the chassis in place, wherein either the plurality of pins or the plurality of mating apertures are positioned on three different sides of the chassis; and heat staking the chassis of the dose counter onto the body by heat staking the plurality of pins in their respective mating apertures. [Emphasis Added]

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This patent application is generally directed to a method of heat staking a chassis of a dose counter onto a body of an inhaler. By way of background to the rejection, the Office Action cites to paragraph 0140 of Anderson (shown below to the left) for its teaching of components of an inhaler body that are heat staked together at points 492a-c and 494a-c. The Office Action acknowledges that Anderson does not disclose a dose counter that is heat staked to the body inhaler, however, the Office Action relies on Bowman (shown below to the right) for its teaching of a dose counter that is mounted to a base of an inhaler, and contends that it would have been obvious to utilize Anderson's heat staking operation for mounting Bowman's dose counter into the inhaler body.



Sole independent claim 1 now recites that "wherein either the plurality of pins or the plurality of mating apertures are positioned on three different sides of the chassis." The Applicant submits that such a feature is advantageous for firmly mounting the dose counter into the inhaler body. In contrast to this feature of claim 1, Anderson's pins 492a-c and apertures 494a-c (**see above**) are each positioned on the same side of their respective parts.

Accordingly, because claim 1 includes features that are neither disclosed nor suggested by the cited references, neither anticipation nor *prima facie* obviousness can be established based on the cited references. The dependent claims that stand rejected should also be allowed at least as being dependent upon an allowable base claim. Reconsideration of claims 1, 2, 5 and 6 is respectfully requested.

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**Conclusion**

In view of the remarks set forth above, the Applicant respectfully submits that this application is now in condition for allowance, which action is respectfully requested. If the Examiner believes an interview will advance the prosecution of this application, it is respectfully requested that the Examiner contact the undersigned to arrange the same.

Respectfully submitted,

/Brett J. Rosen/

Brett J. Rosen, Reg. No. 56,047  
Attorney for Applicant

BJR/pbm

Dated: September 28, 2016

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King of Prussia, PA 19406  
(610) 407-0700

The Director is hereby authorized to charge or credit Deposit Account No. **18-0350** for any additional fees, or any underpayment or credit for overpayment in connection herewith.

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**Electronic Acknowledgement Receipt**

|   |  |
|---|--|
| <b>EFS ID:</b>                              | 27053251   |
| <b>Application Number:</b>                  | 14713643   |
| <b>International Application Number:</b>    |  |
| <b>Confirmation Number:</b>                 | 4229   |
| <b>Title of Invention:</b>                  | DOSE COUNTERS FOR INHALERS, INHALERS AND METHODS OF ASSEMBLY THEREOF |
| <b>First Named Inventor/Applicant Name:</b> | Declan Walsh   |
| <b>Customer Number:</b>                     | 64955  |
| <b>Filer:</b>                               | Brett Rosen/Marianne Friel   |
| <b>Filer Authorized By:</b>                 | Brett Rosen  |
| <b>Attorney Docket Number:</b>              | TEVE-139US12   |
| <b>Receipt Date:</b>                        | 28-SEP-2016  |
| <b>Filing Date:</b>                         | 15-MAY-2015  |
| <b>Time Stamp:</b>                          | 14:31:31   |
| <b>Application Type:</b>                    | Utility under 35 USC 111(a)  |

**Payment information:**

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**File Listing:**

| Document Number | Document Description                                  | File Name                  | File Size(Bytes)/<br>Message Digest                | Multi Part /.zip | Pages (if appl.) |
|-----------------|---|----------------------------|--|------------------|------------------|
| 1               | Amendment/Req. Reconsideration-After Non-Final Reject | TEVE_139US12_AMENDMENT.pdf | 159551<br>2e6dfcb1591c143db60b0e0f3267f24e231e39fb | no               | 5                |

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159551

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**New Applications Under 35 U.S.C. 111**

**If a new application is being filed and the application includes the necessary components for a filing date (see 37 CFR 1.53(b)-(d) and MPEP 506), a Filing Receipt (37 CFR 1.54) will be issued in due course and the date shown on this Acknowledgement Receipt will establish the filing date of the application.**

**National Stage of an International Application under 35 U.S.C. 371**

**If a timely submission to enter the national stage of an international application is compliant with the conditions of 35 U.S.C. 371 and other applicable requirements a Form PCT/DO/EO/903 indicating acceptance of the application as a national stage submission under 35 U.S.C. 371 will be issued in addition to the Filing Receipt, in due course.**

**New International Application Filed with the USPTO as a Receiving Office**

**If a new international application is being filed and the international application includes the necessary components for an international filing date (see PCT Article 11 and MPEP 1810), a Notification of the International Application Number and of the International Filing Date (Form PCT/RO/105) will be issued in due course, subject to prescriptions concerning national security, and the date shown on this Acknowledgement Receipt will establish the international filing date of the application.**



| <b>PATENT APPLICATION FEE DETERMINATION RECORD</b><br>Substitute for Form PTO-875   |   |                                  |           | Application or Docket Number<br>14/713,643 | Filing Date<br>05/15/2015 | <input type="checkbox"/> To be Mailed |
|---|---|----------------------------------|-----------|--|---------------------------|---------------------------------------|
| <b>ENTITY:</b> <input checked="" type="checkbox"/> LARGE <input type="checkbox"/> SMALL <input type="checkbox"/> MICRO  |   |                                  |           |  |                           |                                       |
| <b>APPLICATION AS FILED – PART I</b>  |   |                                  |           |  |                           |                                       |
| (Column 1)  |   | (Column 2)                       |           |  |                           |                                       |
| FOR   | NUMBER FILED  | NUMBER EXTRA                     | RATE (\$) |  | FEE (\$)                  |                                       |
| <input type="checkbox"/> BASIC FEE<br>(37 CFR 1.16(a), (b), or (c))   | N/A   | N/A                              | N/A       |  |                           |                                       |
| <input type="checkbox"/> SEARCH FEE<br>(37 CFR 1.16(k), (i), or (m))  | N/A   | N/A                              | N/A       |  |                           |                                       |
| <input type="checkbox"/> EXAMINATION FEE<br>(37 CFR 1.16(o), (p), or (q))   | N/A   | N/A                              | N/A       |  |                           |                                       |
| TOTAL CLAIMS<br>(37 CFR 1.16(i))  | minus 20 =  | *                                | X \$    = |  |                           |                                       |
| INDEPENDENT CLAIMS<br>(37 CFR 1.16(h))  | minus 3 =   | *                                | X \$    = |  |                           |                                       |
| <input type="checkbox"/> APPLICATION SIZE FEE<br>(37 CFR 1.16(s))   | If the specification and drawings exceed 100 sheets of paper, the application size fee due is \$310 (\$155 for small entity) for each additional 50 sheets or fraction thereof. See 35 U.S.C. 41(a)(1)(G) and 37 CFR 1.16(s). |                                  |           |  |                           |                                       |
| <input type="checkbox"/> MULTIPLE DEPENDENT CLAIM PRESENT (37 CFR 1.16(j))  |   |                                  |           |  |                           |                                       |
| * If the difference in column 1 is less than zero, enter "0" in column 2.   |   |                                  | TOTAL     |  |                           |                                       |
| <b>APPLICATION AS AMENDED – PART II</b>   |   |                                  |           |  |                           |                                       |
| (Column 1)  |   | (Column 2)                       |           | (Column 3)                                 |                           |                                       |
| <b>AMENDMENT</b>  | <b>09/28/2016</b>   | CLAIMS REMAINING AFTER AMENDMENT |           | HIGHEST NUMBER PREVIOUSLY PAID FOR         | PRESENT EXTRA             | RATE (\$)                             |
|   | Total (37 CFR 1.16(i))  | * 4                              | Minus     | ** 20                                      | = 0                       | X \$80 =                              |
|   | Independent (37 CFR 1.16(h))  | * 1                              | Minus     | *** 3                                      | = 0                       | X \$420 =                             |
|   | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))  |                                  |           |  |                           |                                       |
|   | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))  |                                  |           |  |                           |                                       |
| TOTAL ADD'L FEE   |   |                                  |           |  |                           | <b>0</b>                              |
| (Column 1)  |   | (Column 2)                       |           | (Column 3)                                 |                           |                                       |
| <b>AMENDMENT</b>  |   | CLAIMS REMAINING AFTER AMENDMENT |           | HIGHEST NUMBER PREVIOUSLY PAID FOR         | PRESENT EXTRA             | RATE (\$)                             |
|   | Total (37 CFR 1.16(i))  | *                                | Minus     | **   | =                         | X \$    =                             |
|   | Independent (37 CFR 1.16(h))  | *                                | Minus     | ***  | =                         | X \$    =                             |
|   | <input type="checkbox"/> Application Size Fee (37 CFR 1.16(s))  |                                  |           |  |                           |                                       |
|   | <input type="checkbox"/> FIRST PRESENTATION OF MULTIPLE DEPENDENT CLAIM (37 CFR 1.16(j))  |                                  |           |  |                           |                                       |
| TOTAL ADD'L FEE   |   |                                  |           |  |                           |                                       |
| * If the entry in column 1 is less than the entry in column 2, write "0" in column 3.<br>** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 20, enter "20".<br>*** If the "Highest Number Previously Paid For" IN THIS SPACE is less than 3, enter "3".<br>The "Highest Number Previously Paid For" (Total or Independent) is the highest number found in the appropriate box in column 1. |   |                                  |           |  |                           |                                       |

LIE  
CAROL BARNES

This collection of information is required by 37 CFR 1.16. The information is required to obtain or retain a benefit by the public which is to file (and by the USPTO to process) an application. Confidentiality is governed by 35 U.S.C. 122 and 37 CFR 1.14. This collection is estimated to take 12 minutes to complete, including gathering, preparing, and submitting the completed application form to the USPTO. Time will vary depending upon the individual case. Any comments on the amount of time you require to complete this form and/or suggestions for reducing this burden, should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, U.S. Department of Commerce, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. **SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.**

If you need assistance in completing the form, call 1-800-PTO-9199 and select option 2.